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Brandy Diiken

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Gudmundur Johannsson et al

Paper No.:

Serial No. 09/050,366

Group Art Unit: 1653

Filed: March 31, 1998

Examiner: Abdel A Mohamed

For: Use of Growth Hormone

DECLARATION UNDER 37 C.F.R. 1.132 OF
DR. SIGBRITT A. M. WERNER

Box RCE
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Dr. Sigbritt A. M. Werner declares that:

1. She enrolled as a medical candidate date in 1962 at Karolinska Institutet, Stockholm, Sweden and in 1974 she was awarded a Medical Doctor degree from Karolinska Institutet. In 1974, she was also certified as a Specialist competent in Internal Medicine and Endocrinology, and in 1977 she was awarded Docent in Endocrinology. In 1985, she became Chief Physician at Karolinska Hospital, Stockholm, Sweden. In 1993, she became a University Lecturer in Endocrinology at Karolinska Institutet. In 1996, she became Chief Physician at the Center for Metabolism and Endocrinology at Huddinge University Hospital, Stockholm, Sweden, and in 1999 she became a Professor in Endocrinology at Karolinska Institutet. She was elected ProRektor/Vice President at Karolinska Institutet July 2001. Over the course of her career, she has published more than 120 scientific, refereed, original articles relating to, inter alia, hypothalamus, pituitary, the parathyroid and adrenal glands, and primary cortisol resistance and approximately 30 reference articles and chapters for books in classic

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endocrinology. She also currently serves as the main editor for a textbook in clinical endocrinology to be published in Swedish in the autumn of 2003.

2. She is familiar with the present application Serial No. 09/050,366 filed March 31, 1998, is familiar with the Official Action dated April 16, 2002, and the reference cited therein including Johansson et al, *Metabolism*, Vol 44, No 9, Pages 1126-1129 (September 1995).

3. In response to the comments set forth by the Examiner in the Official Action dated April 16, 2002, she further declares that based on her experience in the medical fields and particularly in the field of endocrinology, it is her opinion that growth hormone deficient patients are distinct from patients who are not growth hormone deficient. Specifically, growth hormone deficient patients do not produce growth hormone and therefore their hormone levels and their therapeutic response to growth hormone administration differ significantly from the hormone levels and therapeutic response to growth hormone administration in a patient who is not growth hormone deficient. Thus, a therapeutic response to growth hormone administration in a growth hormone deficient patient cannot be used to predict a response to growth hormone administration in a patient who is not growth hormone deficient. Specifically, the effect of growth hormone administration on insulin resistance in a growth hormone deficient patient cannot be used to predict an effect of growth hormone administration on insulin resistance in a patient who is not growth hormone deficient.

4. Also, based on her experience in the field of endocrinology, it is her opinion that an individual who has the metabolic syndrome does not inherently exhibit growth hormone deficiency, and an individual who has growth hormone deficiency does not inherently exhibit the metabolic syndrome.

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5. Further, based on her experience in the field of endocrinology, it is her opinion that Johansson et al do not teach or suggest that individuals with metabolic syndrome have insulin resistance and that this article cannot be used to suggest growth hormone administration to decrease insulin resistance in individuals having the Metabolic Syndrome.

6. She further declares that all statements made herein of her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,

August 20 2002

Date

Sigbritt Werner

Dr. Sigbritt A. M. Werner